IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

YURIAH DRYE, Individually and as the Surviving Parent of, KASEI DRYE, deceased, and YURIAH DRYE, as Personal Representative of the ESTATE OF KASEI DRYE,

Plaintiff,

Case No.:

v.

ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; MEAD JOHNSON & COMPANY, LLC; MEAD JOHNSON NUTRITION COMPANY,

Defendants,
_____/

PLAINTIFF'S COMPLAINT FOR DAMAGES

This action arises out of the injuries suffered by Plaintiff's premature infant, who was fed Defendants' cow's-milk-based infant formula and/or fortifier. Necrotizing Enterocolitis (hereinafter "NEC") is a deadly intestinal disease characterized by inflammation and injury of the gut wall barrier that may advance to necrosis and perforation of the gut. Advanced cases of NEC may lead to surgery and to death. Significantly higher rates of NEC have been found in premature or preterm babies with low birth weights who are fed cow's milk-based formula or fortifier products. The companies who manufacture these products often

intentionally mislabel and misrepresent the contents of the products both to the public at-large and to the health care community, passing off these deadly products as something similar to or even superior to human breast milk. Tragically, baby Kasei Drye (hereinafter "Baby Drye"), who was premature at birth, was fed these cow's milk-based products, developed NEC, and suffered significant injuries and death as a result.

Plaintiff YURIAH DRYE, Individually and as the Surviving Parent of, KASEI DRYE, deceased, and YURIAH DRYE, as Personal Representative of the ESTATE OF KASEI DRYE, brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendants' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, failure to warn, and/or sale of the Defendants' cow's milk-based products (hereinafter "Cow's milk-based Formula," "Cow's milk-based Fortifier," or collectively "Cow's Milk-Based Products").

GENERAL ALLEGATIONS

YURIAH DRYE, Individually and as the Surviving Parent of, KASEI DRYE, deceased, and YURIAH DRYE, as Personal Representative of the ESTATE OF KASEI DRYE, (hereinafter "Plaintiff"), by and through the undersigned counsel, brings this Complaint against Defendant Abbott Laboratories, Defendant Abbott

Laboratories, Inc., Defendant Mead Johnson & Company, LLC, and Defendant Mead Johnson Nutrition Company and upon information and belief and based upon the investigation of counsel to date, would set forth as grounds the following:

JURISDICTION AND VENUE

1. This is an action for damages which exceeds the sum of $75,000.00, exclusive of costs, interest, and attorneys' fees.

2. This Court has jurisdiction over this case pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and the Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of $75,000.00.

3. This Court has personal jurisdiction over Defendant Abbott Laboratories, Inc. Defendant is incorporated under the laws of Illinois and is authorized to conduct business and does conduct business in the State of Georgia. Defendant has marketed, promoted, distributed, and/or sold its Cow's Milk-Based Products in the State of Georgia, and Defendant has sufficient minimum contacts with this state and/or sufficiently avails itself of the markets in the state through its promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

4. This Court has personal jurisdiction over Defendant Abbott Laboratories. Defendant is incorporated under the laws of Illinois and is conducts business in the State of Georgia. Defendant has marketed, promoted, distributed,

and/or sold its Cow's Milk-Based Products in the State of Georgia, and Defendant has sufficient minimum contacts with this state and/or sufficiently avails itself of the markets in the state through its promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

5. This Court has personal jurisdiction over Defendants Mead Johnson & Company, LLC and Defendant Mead Johnson Nutrition Company. Defendants are authorized to conduct business and do conduct business in the State of Georgia. Defendants have marketed, promoted, distributed, and/or sold their Cow's Milk-Based Products in the State of Georgia, and Defendants have sufficient minimum contacts with this state and/or sufficiently avail themselves of the markets in the state through its promotion, sales, distribution, and marketing within this state to render exercise of jurisdiction by this Court permissible.

6. Venue of this action is proper in this Court pursuant to 28 U.S.C. §§1391 (a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district and because Plaintiff resides in this district.

PLAINTIFF

7. Baby Drye was born prematurely at Grady Hospital in Atlanta, Georgia on January 31, 2021. Baby Drye developed NEC after being fed Defendants' Cow's Milk-Based Products while in the hospital. At all times material hereto, Baby Drye

was domiciled in and a citizen of the State of Georgia.

8. Plaintiff Yuriah Drye is Baby Drye's mother, is domiciled in and a citizen of State of Georgia, and resides in Fulton County, Georgia. Baby Drye's mother, individually brings this action to recover for Baby Drye's medical expenses, as well as all claims of Baby Drye, a deceased minor, which are the direct and proximate result of consumption of Defendants' unreasonably dangerous cow's milk-based preterm infant nutrition products.

DEFENDANTS

9. Defendants Abbott Laboratories and Abbott Laboratories, Inc. (collectively "Abbott") were at all times material hereto and are now corporations duly organized, incorporated, and existing under the laws of the State of Illinois and/or the State of Delaware, with their principal place of business and headquarters in the State of Illinois and are thus residents, citizens and domiciliary of Illinois. Abbott manufactures, designs, formulates, prepares, tests, provides instructions for, markets, labels, packages, sells, and/or places into the stream of commerce in all fifty states, including Illinois and Georgia, premature infant formula and premature infant milk fortifier under the Similac brand name.

10. Defendant Abbott advertises that it provides the "#1 Formula Brand, Backed by Science" and claims to have "over 90 years of innovations" in infant formula.

11. Defendants, Mead Johnson & Company, LLC, and Mead Johnson Nutrition Company, (collectively "Mead Johnson") are companies based in Illinois that manufacture, design, formulate, prepare, test, provide instructions, market, label, package, sell, and/or place into the stream of commerce in all fifty states, including Illinois and Georgia, premature infant formula including Enfamil and Enfamil Human Milk Fortifier. Upon information and belief, at all times material hereto, the sole member of Mead Johnson & Company, LLC is Mead Johnson Nutrition Company.

12. Mead Johnson Nutrition Company self-proclaims to be recognized as "a world leader in pediatric nutrition" and traces its history back to the company's founding in 1905 by Edward Mead Johnson, Sr. It claims to be the "only global company focused primarily on infant and child nutrition" and that its "singular devotion has made our flagship 'Enfa' line the leading infant nutrition brand in the world." Boasting "more than 70 products in over 50 countries," it claims that its "products are trusted by millions of parents and healthcare professionals around the world."

FACTUAL ALLEGATIONS

The Science and Scope of the Problem

13. According to the World Health Organization ("WHO"), babies born prematurely, or "preterm," are defined as being born alive before 37 weeks of

pregnancy are completed, like Baby Drye. The WHO estimates that approximately 15 million babies are born preterm every year and that this number is rising.

14. Nutrition for preterm babies, especially those who have a very low birth weight (under 1500 grams) or extremely low birth weight (under 1000 grams), is significantly important. Since the United States ranks in the top ten countries in the world with the greatest number of preterm births, the market of infant formula and fortifiers is particularly vibrant.

15. Science and research have advanced in recent years confirming strong links between cow's milk-based products and NEC causing and/or substantially contributing to death in preterm and severely preterm, low-weight infants, along with many other health complications and long-term risks to these babies. Additionally, advances in science have created alternative fortifiers that are derived from human milk and non-cow's milk-based products, however, the manufacturers of the Cow's Milk-Based Products continue to promote and sell the Cow's Milk-Based Product versions.

16. As far back as 1990, a prospective, multicenter study on 926 preterm infants found that NEC was **six to ten times more** common in exclusively formula-fed babies than in those fed breast milk alone and **three times more common** than in those who received formula plus breast milk. The study also found that NEC was rare in babies born at more than 30 weeks gestation whose diet included breast

milk, but was **20 times more common** in those fed cow's milk-based formula only. A. Lucas, T. Cole, *Breast Milk and Neonatal Necrotizing Enterocolitis*, LANCET, 336: 1519-1523 (1990) (emphasis added).

17. A study published in 2009 evaluated the health benefits of an exclusively human milk-based diet as compared to a diet with both human milk and cow's milk-based products in extremely premature infants. The results show that preterm babies fed an exclusively human milk-based diet were **90% less likely** to develop surgical NEC as compared to a diet that included some cow's milk-based products. S. Sullivan, *et al*, *An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, JOURNAL OF PEDIATRICS, 156: 562-7 (2010) (emphasis added).

18. In 2011, the U.S. Surgeon General published a report titled, "The Surgeon General's Call to Action to Support Breastfeeding." In it, the Surgeon General warned that "for vulnerable premature infants, **formula feeding is associated with higher rates** of necrotizing enterocolitis (NEC)." U.S. Dep't of Health & Human Serv., Off. of Surgeon Gen., "The Surgeon General's Call to Action to Support Breastfeeding," p.1, (2011) (emphasis added). This same report stated that premature infants who are not breast-fed are **138% more likely** to develop NEC. *Id*.

19. In 2012, the American Academy of Pediatrics issued a policy statement

that all premature infants should be fed an exclusive human milk diet because of the risk of NEC associated with the consumption of Cow's Milk-Based Products. The Academy stated that "[t]he potent benefits of human milk are such that all preterm infants should receive human milk... If the mother's own milk is unavailable ...pasteurized donor milk should be used." *Breastfeeding and the Use of Human Milk*, PEDIATRICS, 129:e827-e84l (2012).

20. Further, a study published in 2013 showed that all 104 premature infants participating in the study receiving an exclusive human-milk based diet exceeded targeted growth standards and length and weight and head circumference gain. The authors concluded that "this study provides data showing that **infants can achieve and mostly exceed targeted growth standards when receiving an exclusive human milk-based diet**." A. Hair, *et al*, *Human Milk Feeding Supports Adequate Growth in Infants ≤1250 Grams Birthweight*, BMC RESEARCH NOTES, 6:459 (2013) (emphasis added). Thus, inadequate growth was proven to be a poor excuse for feeding Cow's Milk-Based Formula, but the practice has largely continued due to extensive and aggressive marketing campaigns conducted by infant formula such as the Defendants.

21. Another study published in 2013 reported the first randomized trial in extremely premature infants of exclusive human milk versus preterm cow's milk-based formula. The study found a **significantly higher rate** of surgical NEC in

infants receiving the cow's milk-based preterm formula and supported the use of exclusive human milk diet to nourish extremely preterm infants in the NICU. E.A. Cristofalo, *et al*, *Randomized Trial in Extremely Preterm Infants*, J PEDIATR., 163(6):1592-1595 (2013) (emphasis added).

22. In another study published in 2014, it was reported that NEC is "a devastating disease of premature infants and is associated with **significant morbidity and mortality**. While the pathogenesis of NEC remains incompletely understood, it is well established that the risk is increased by the administration of infant formula and decreased by the administration of breast milk." Misty Good, *et al*., *Evidence Based Feeding Strategies Before and After the Development of Necrotizing Enterocolitis*, EXPERT REV. CLIN. IMMUNOL., 10(7): 875-884 (2014 July) (emphasis added). The same study found that NEC "is the **most frequent and lethal gastrointestinal disorder** affecting preterm infants and is characterized by intestinal barrier disruption leading to intestinal necrosis, multi-system organ failure and death." *Id.* The study noted that "NEC affects 7-12% of preterm infants weighing less than 1500 grams, and the frequency of disease appears to be either stable or rising in several studies." *Id.* "The typical patient who develops NEC is a "premature infant who displays a rapid progression from mild feeding intolerance to systemic sepsis, and **up to 30% of infants will die from this disease**." *Id.* Advances in formula development have made it possible to prevent necrotizing enterocolitis, and

the "exclusive use of human breast milk is recommended for all preterm infants and is associated with a significant decrease in the incidence of NEC." *Id.*

23. In yet another study published in 2014, it was reported that an exclusive human milk diet, devoid of Cow's Milk-Based Products, was associated with "lower mortality and morbidity" in extremely preterm infants without compromising growth and should be considered as an approach to nutritional care of these infants. Steven Abrams, *et al*., *Greater Mortality and Morbidity in Extremely Preterm Infants Fed a Diet Containing Cow Milk Protein Products*, BREASTFEEDING MEDICINE, 9(6):281-286 (2014).

24. In 2016, a large study supported previous findings that an exclusive human milk diet in extreme preterm infants dramatically decreased the incidence of both medical and surgical NEC. This was the first study to compare rates of NEC after a feeding protocol implementation at multiple institutions and years of follow-up using an exclusive human milk diet. The authors concluded that the use of an **exclusive human milk diet is associated with "significant benefits"** for extremely preterm infants and while evaluating the benefits of using an exclusive human milk-based protocol, "it appears that there were **no feeding-related adverse outcomes**." Hair, *et al*, *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk Based Diet*, BREASTFEEDING MEDICINE, 11-2 (2016) (emphasis added).

25. A publication by the American Society for Nutrition, in 2017, noted that human milk has "been acknowledged as the best source of nutrition for preterm infants and those at risk for NEC." The study compared the results from two randomized clinical trials on preterm infants with severely low weight (between 500 and 1250 grams at birth) and compared the effect of cow's milk-based preterm infant formula to human milk as to the rate of NEC. Both trials found that an **exclusive human milk diet resulted in a much lower incidence of NEC**. While the study noted that cow's milk-based preterm formulas provided consistent calories and were less expensive than human milk-based products, the **cow's milk-based products significantly increase the risk of NEC and death**. The study also noted the **"exponential" health care costs** associated with NEC and noted data from the U.S. from 2011-2012 that showed that the cost of NEC is $180,000 to $198,000 per infant and nearly doubles to $313,000 per infant for surgically treated NEC. Further, NEC survivors accrue substantially higher outpatient costs. Jocelyn Shulhan, *et al*, *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ASN ADV. NUTR., 8(1):80-91 (2017) (emphasis added).

26. The WHO and United Nation's International Children's Emergency Fund (UNICEF) held a meeting more than two decades ago to address concerns over the marketing of breast-milk substitutes. The WHO Director concluded the meeting

with the following statement, "**In my opinion, the campaign against bottle-feed advertising is unbelievably more important than the fight against smoking advertisement**." Jules Law, *The Politics of Breastfeeding: Assessing Risk, Dividing Labor*, JSTOR SIGNS, vol. 25, no. 2: 407-50 (2000) (emphasis added).

27. Recognizing the abuse and dangers of the marketing of infant formula, in 1981, the World Health Assembly ("WHA"), the decision-making body of the world's Member States, developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk and outlawed any advertising or promotion of breast milk substitutes to the general public. Pursuant to Article 5.1 of the Code, advertising of breast-milk substitutes is specifically prohibited: "**There should be no advertising or other form of promotion to the general public** [of breast milk substitutes]." (emphasis added). In Article 5.2, the Code states that "manufacturers and distributors should not provide, **directly or indirectly**, to pregnant women, mothers or members of their families, samples of products within the scope of this Code." In addition, the Code expressly prohibits, "point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales…" *See* Int'l Code of Marketing of Breast-Milk Substitutes, May 21, 1981, WHA 34/1981/REC/2, Art.5.3.

28. The World Health Organization's 2018 Status Report on this issue noted that "despite ample evidence of the benefits of exclusive and continued breastfeeding for children, women, and society, far too few children are breastfed as recommended." The Status Report states that "**a major factor undermining efforts to improve breastfeeding rates is continued and aggressive marketing of breast-milk substitutes**," noting that in 2014, the global sales of breast-milk substitutes amounted to **US $44.8 billion** and "is expected to rise to **US $70.6 billion** by 2019." *Marketing of Breast-milk Substitutes: Nat'l Implementation of the Int'l Code, Status Report 2018*. Geneva: World Health Org., 2018, p.21 (emphasis added).

29. Recognizing a shift in the medical community towards an exclusive human based diet for preterm infants, the Defendants began heavily promoting "human milk fortifiers," a name which misleadingly suggests that the product is derived from human milk, instead of being derived from Cow's Milk.

30. The Defendants have designed competing, systematic, powerful, and misleading marketing campaigns to persuade physicians and parents to believe that: (1) Cow's Milk-based formula and fortifiers are safe; (2) Cow's Milk-Based Products are equal, or even superior, substitutes to breastmilk; and (3) physicians consider their Cow's Milk-Based Products a first choice. Similarly, the Defendants market their products for preterm infants as necessary for growth, and perfectly safe for preterm infants, despite knowing of the extreme risks posed by Cow's Milk-

Based Products and failing to warn of the deadly disease of NEC.

31. Thus, despite the existence of alternative and safe human milk-based fortifiers, the Defendants continue to market and/or sell the Cow's Milk-Based Products under the guise of being a safe product for newborns and despite knowing the significant health risk posed by ingesting these products, especially to preterm, low weight infants like Baby Drye.

The Inadequate Warnings

32. Defendants promote the use of its preterm infant Cow's Milk-Based Products to parents, physicians, hospitals, and medical providers as safe products that are specifically needed by preterm infants for adequate growth.

33. Despite the knowledge of the significant health risks posed to preterm infants ingesting the Cow's Milk-Based Products, including the significant risk of NEC, Defendants did not warn parents or medical providers of the risk of NEC in preterm infants, nor did Defendants provide any instructions or guidance on how to properly use its Cow's Milk-Based Products so as to lower the risk or avoid NEC.

34. In fact, Defendants did not provide any warning in their labeling, websites, or marketing that warns that their Cow's Milk-Based Products exponentially increase the risk of NEC in preterm infants, or that human breast milk, donor breast milk, and human breast milk-based formulas and fortifiers are much safer for preterm babies than its Cow's Milk-Based Products.

Baby Drye and the Dangerous, Defective Products

35. Baby Drye was born prematurely, at 29 weeks gestation, at Grady Hospital in Atlanta, Georgia on January 31, 2021. At birth, Baby Drye weighed 990 grams.

36. After initially feeding him with maternal breastmilk, Grady Hospital fed Baby Drye with preterm formula beginning on or about February 2, 2021.

37. On February 11, 2021, Baby Drye exhibited symptoms of NEC, specifically abdominal distention, tenderness, and firmness. An x-ray showed pneumatosis and portal venous gas.

38. On or about February 14, 2021, Baby Drye was diagnosed with NEC and transferred to the NICU at Children's Hospital of Atlanta ("CHOA") at Egleston for further testing and care.

39. On that same day, Baby Drye underwent an exploratory laparotomy at CHOA. The exploratory surgery revealed extensive NEC.

40. During the same surgery, the surgeon at CHOA resected portions of Baby Drye's small bowel, giving him an ostomy, and retained approximately 15 centimeters of small bowel.

41. For the remaining days of his life, Baby Drye was treated with antibiotics.

42. As a result of NEC, Baby Drye died on February 22, 2021.

43. At the time of his death from NEC, Baby Drye's parent was unaware of the fact that the Defendants' Cow's Milk-Based Products Baby Drye was fed caused or substantially contributed to his development of NEC and resulting injuries and death.

COUNT I: STRICT LIABILITY
DESIGN DEFECT AS TO ABBOTT DEFENDANTS

44. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

45. At all times material to this action, Abbott Defendants were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers, including Baby Drye.

46. Abbott Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

47. At all times material to this action, the Cow's Milk-Based Products manufactured, distributed and/or sold by Abbott Defendants, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

48. Abbott Defendants specifically marketed and created their Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants,

like Baby Drye.

49. Abbott Defendants Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

50. Prior to Baby Drye's birth, Abbott Defendants were aware or should have been aware that their Cow's Milk-Based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet took no steps to prevent the use of these products in such situations.

51. Abbott Defendants knew or should have known that the use of their Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC.

52. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for preterm infants like Baby Drye.

53. Despite the foregoing, Abbott Defendants continued to sell and market their defective and/or unreasonably dangerous products to preterm infants.

54. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Baby Drye, to risks of serious bodily injury and death;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of that product when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the product;

f. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants failed to inspect or test its products with sufficient care.

55. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable dangerous condition, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories and Abbott Laboratories, Inc. for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT II: NEGLIGENCE AS TO ABBOTT DEFENDANTS

56. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

57. Abbott Defendants, as the manufacturer and/or seller of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

58. Abbott Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert, and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

59. Abbott Defendants, directly or indirectly, negligently, and/or

defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

60. Defendants breached the duty owed to Plaintiff and acted negligently in their actions, including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data to determine if its products were safe for preterm infants;

d. Failing to collect data to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of their products causing NEC;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of their products causing NEC;

h. Failing to stop or deter their products from being fed to preterm infants like Baby Drye;

i. Failing to provide evidence-based instructions or guidance on when or how a preterm infant should be transitioned to the products;

j. Failing to continuously and vigorously study its cow's milk-based products in order to avoid NEC in premature infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

l. Failing to adopt an adequate or sufficient quality control program; and/or

m. Failing to inspect or test their products with sufficient care.

61. Abbott Defendants knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Baby Drye.

62. Abbott Defendants knew or should have known that the use of their Cow's Milk-Based Products with preterm infants was unreasonably dangerous in

that their Cow's Milk-Based Products significantly increased the risk of NEC.

63. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC, which far outweighed the products' benefits for premature infants like Baby Drye.

64. As a direct and proximate result of the negligence of Abbott Defendants, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories and Abbott Laboratories, Inc. for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT III: STRICT LIABILITY FAILURE TO WARN AS TO ABBOTT DEFENDANTS

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott Defendants, as the manufacturers and/or sellers of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including, but not limited to, the risk of NEC.

67. Abbott Defendants, as the manufacturers and/or sellers of Cow's Milk Product, were unreasonable in relying upon any intermediary, including physicians,

other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in their Cow's Milk-Based Products, as the magnitude of the risk involved is using Defendants' Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury.

68. Abbott Defendants, as the manufacturers and/or sellers of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers of their Cow's Milk-Based Products.

69. Defendants owed a duty to provide warnings and instructions on their Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the products to health care providers and staff using these products in a NICU, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including, but not limited to, the risk of NEC.

70. Rather than provide adequate warnings, Abbott Defendants developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions

and/or warnings from the end user.

71. In addition and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not used such a dangerous product.

72. Abbott Defendants, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

73. Abbott Defendants, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infants.

74. Abbott Defendants, through their knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to, NEC.

75. Abbott Defendants breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's Milk-Based Products, including but not limited to the following acts:

a. Providing **no warnings** regarding the risk of NEC;

b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products with preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendants' Cow's Milk Product;

e. Failed to provide instructions to consumers and health care providers that the Defendants' products carried a significant risk that their Cow's Milk-Based Products exponentially increased their baby's risk of developing NEC;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn that the use of Cow's Milk-Based Products significantly increasing the risk of NEC, and they fail to provide any details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that their Cow's Milk-Based Products are known to significantly increase the risk of NEC when compared to Human Milk in preterm infants;

h. Failed to provide well researched and well-established studies that linked their Cow's Milk-Based Products to NEC in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of their products;

j. Failed to otherwise warn physicians, and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

k. Failed to send out "Dear Dr." letters warning of the risks of NEC and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers and health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

76. As a direct and proximate result of Abbott Defendants' failure to warn, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Abbott Laboratories and Abbott Laboratories, Inc. for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT IV: STRICT LIABILITY DESIGN DEFECT AS TO MEAD JOHNSON DEFENDANTS

77. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

78. At all times material to this action, Defendants Mead Johnson were engaged in the sale, and/or marketing and/or design, and/or manufacture, and/or distribution of Cow's Milk-Based Products, which are defectively designed and/or unreasonably dangerous to consumers, including Baby Drye.

79. Defendants Mead Johnson, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

80. At all times material to this action, the Cow's Milk-Based Products

manufactured, distributed and/or sold by Defendants Mead Johnson, were in a defective and/or unreasonably dangerous condition at the time the products were placed in the stream of commerce for nutritional use for preterm infants.

81. Defendants Mead Johnson specifically marketed and created their Cow's Milk-Based Products for use as nutrition and nutritional supplements for preterm infants, like Baby Drye.

82. Defendants Mead Johnson's Cow's Milk-Based Products are expected to and do reach the user without substantial change affecting that defective and/or unreasonably dangerous condition.

83. Prior to Baby Drye's birth, Defendants Mead Johnson were aware or should have been aware that their Cow's Milk-Based Products were not safe for use, as they were used, with nutrition or nutritional support in preterm infants, yet they took no steps to prevent the use of these products in such situations.

84. Defendants Mead Johnson knew or should have known that the use of their Cow's Milk-Based Products with preterm infants were unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC and death.

85. Furthermore, scientific data and well-researched studies have concluded that the Cow's Milk-Based Products of the Defendants carried unreasonable risks of NEC and death, which far outweighed the products' benefits

for extremely premature infants like Baby Drye.

86. Despite the foregoing, the Defendants continued to sell and market their defective and/or unreasonably dangerous products to extremely preterm infants.

87. The products were defectively manufactured and/or designed and/or unreasonably dangerous, including, but not limited to the following particulars:

a. The products did not perform as safely as an ordinary consumer would expect when used in the intended or reasonably foreseeable manner, such that the use of Cow's Milk-Based Products as nutrition or nutritional supplements in preterm infants significantly increased the risk of NEC and death;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants, such as Baby Drye, to risks of serious bodily injury and death;

c. The products failed to meet legitimate, commonly held, minimum safety expectations of the products when used in an intended or reasonably foreseeable manner;

d. Defendants failed to utilize economical and technically available safer design alternatives for preterm infant formula and fortifiers;

e. The products were manifestly unreasonable in that the risk of harm so clearly exceeded the products' utility that a reasonable consumer, informed of those risks and utility, would not purchase the products;

f. Defendants failed to adopt an adequate or sufficient quality control program; and/or

g. Defendants failed to inspect or test their products with sufficient care.

86. As a direct and proximate cause of the Cow's Milk-Based Product's unreasonable dangerous condition, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT V: NEGLIGENCE AS TO MEAD JOHNSON DEFENDANTS

87. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

88. Defendants Mead Johnson, as the manufacturers and/or sellers of Cow's Milk Product, owed a duty to the consuming public in general, and Plaintiff

in particular, to exercise reasonable care to design, test, manufacture, inspect, and/or to distribute a product free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

89. Defendants Mead Johnson, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific discoveries and are presumed to know the result of all such advances.

90. Defendants Mead Johnson, directly or indirectly, negligently and/or defectively made, created, manufactured, designed, assembled, tested, marketed and/or sold the subject Cow's Milk-Based Products.

91. Defendants Mead Johnson breached the duty owed to Plaintiff and acted negligently in their actions, including, but not limited to, the following:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting preterm infants to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data to determine if their products were safe for preterm infants;

d. Failing to collect data to determine when and how their products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of their products causing NEC;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of their products causing NEC;

h. Failing to stop or deter their products from being fed to extremely preterm infants like Baby Drye;

i. Failing to provide evidence-based instructions or guidance on when or how an extremely preterm infant should be transitioned to the products;

j. Failing to continuously and vigorously study its Cow's Milk Products in order to avoid NEC and death in preterm infants;

k. Failing to utilize economical and technically available safer manufacturing and/or design alternatives for the preterm infant formula and fortifier;

l. Failing to adopt an adequate or sufficient quality control program; and/or

m. Failing to inspect or test their products with sufficient care.

92. Defendants Mead Johnson knew or should have known that their products were to be used as nutrition and nutritional supplements with preterm infants, like Baby Drye.

93. Defendants Mead Johnson knew or should have known that the use of their Cow's Milk-Based Products with preterm infants was unreasonably dangerous in that their Cow's Milk-Based Products significantly increased the risk of NEC and death.

94. Furthermore, scientific data and well researched studies have concluded that the Cow's Milk-Based Products of the Defendants Mead Johnson carried unreasonable risks of NEC and death, which far outweighed the products' benefits for extremely preterm infants like Baby Drye.

95. As a direct and proximate result of the negligence of Defendants Mead Johnson, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VI: FAILURE TO WARN AS TO MEAD JOHNSON DEFENDANTS

96. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

97. Defendants Mead Johnson, as the manufacturers and/or sellers of Cow's Milk-Based Products, owed a duty to the consuming public in general, and Plaintiff in particular, to properly warn and provide adequate warnings or instructions about the dangers and risks associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC and death.

98. Defendants Mead Johnson, as the manufacturers and/or sellers of Cow's Milk Products, were unreasonable in relying upon any intermediary, including physicians, other health care providers or health care staff, to fully warn the end user of the hidden dangers and risks in its Cow's Milk-Based Products, as the magnitude of the risk involved is using Defendants' Cow's Milk-Based Products with preterm infants is significant and involves the real danger of serious bodily injury and death.

99. Defendants Mead Johnson, as the manufacturers and/or sellers of Cow's Milk Products, owed a duty to fully warn and instruct any intermediary, including physicians, other health care providers or health care staff, of the significant dangers in its Cow's Milk-Based Products.

100. Defendants Mead Johnson owed a duty to provide warnings and instructions on their Cow's Milk-Based Products marketed and/or sold for use with preterm infants that adequately communicated information on the dangers and safe use of the product to health care providers and staff using these products in a NICU, taking into account the characteristics of, and the ordinary knowledge common to, such prescribing health care providers and administering health care staff and to specifically warn of the risks and danger associated with the use of Cow's Milk-Based Products with preterm infants, specifically including but not limited to the risk of NEC and death.

101. Rather than provide adequate warnings, Defendants Mead Johnson developed relationships which included incentives and financial gain to health care providers and facilities for using their Cow's Milk-Based Products within the NICU, such that health care providers and facilities had an incentive to withhold any instructions and/or warnings from the end user.

102. In addition and/or in the alternative, if healthcare providers and health care staff had been properly instructed and warned of the risks associated with the use of Cow's Milk-Based Products with preterm infants, they would have not used such a dangerous product.

103. Defendants Mead Johnson, as manufacturers, have a duty to hold the knowledge and skill of an expert and are obliged to keep abreast of any scientific

discoveries and are presumed to know the result of all such advances.

104. Defendants Mead Johnson, through their own testing and studies, consultants and experts, and/or knowledge of the scientific literature, as more specifically set forth in **The Science and Scope of the Problem** Section knew of the significant risk of NEC with preterm infants and death.

105. Defendants Mead Johnson, through their knowledge, review, and survey of the scientific literature, as detailed in **The Science and Scope of the Problem** Section, knew that the use of Cow's Milk-Based Products with preterm infants could cause severe injury, including but not limited to NEC and death.

106. Defendants Mead Johnson breached the foregoing duties and failed to provide proper warnings and/or instructions of their Cow's Milk-Based Products, including but not limited to the following acts:

a. Providing **no warnings** regarding the risk of NEC and death;

b. Providing inadequate labeling that failed to warn of the risks of use of Cow's Milk-Based Products and preterm infants, including but not limited to NEC;

c. Failed to provide proper instructions or guidelines or studies, or data on when and how to feed its products to preterm infants in order to decrease the risk of NEC and/or death;

d. Failed to insert a warning or instruction that parents needed to be provided an informed choice between the safety of human milk versus the dangers of the Defendants' Cow's Milk-Based Products;

e. Failed to provide instructions to consumers and health care that the Defendants' products carried a significant risk that its Cow's Milk-Based Products could cause their baby to develop NEC and die;

f. The warnings and instructions are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct on certain conditions, but do not warn on the use of Cow's Milk-Based Products significantly increasing the risk of NEC and death and fail to provide details on how to avoid such harm;

g. Failed to contain a large and prominent "black box" type warning that their Cow's Milk-Based Products are known to significantly increase the risk of NEC and death when compared to Human Milk in preterm infants;

h. Failed to provide well researched and well-established studies that linked their Cow's Milk-Based Products to NEC and death in preterm infants;

i. Failed to cite to or utilize current up-to-date medical data on the proper and safe use of their product;

j. Failed to otherwise warn physicians and healthcare providers of the extreme risks associated with feeding preterm infants Cow's Milk-Based Products;

k. Failed to send out "Dear Dr." letters warning of the risks NEC and death and the current scientific research and data to better guide the hospitals and physicians to better care for the extremely preterm infants;

l. Failed to advise physicians and healthcare providers that Cow's Milk-Based Products are not necessary to achieve growth and nutritional targets for preterm infants; and/or

m. Failed to contain sufficient instructions and warnings on the Cow's Milk-Based Products such that health care providers health care staff were not properly warned of the dangers of NEC with use of Cow's Milk-Based Products and preterm infants.

107. As a direct and proximate result of Defendants Mead Johnson's failure

to warn, Baby Drye suffered serious bodily injury and death.

WHEREFORE, Plaintiff, by and through undersigned counsel, demands judgment against Defendants Mead Johnson and Company, LLC and Mead Johnson Nutrition Company, for all applicable damages, costs of this action, post-judgment interest, and trial by jury.

COUNT VII: PUNITIVE DAMAGES

108. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

109. At all material times, Defendants knew or should have known that their Cow's Milk-Based Products are inherently dangerous to preterm infants.

110. Despite such knowledge, the Defendants continued to aggressively market their Cow's Milk-Based Products to consumers without disclosing its dangerous side effects when there existed safer alternative products.

111. Despite Defendants' knowledge of their Cow's Milk-Based Products defective and unreasonably dangerous nature, Defendants continued to test, design, develop, manufacture, label, package, promote, market, sell and distribute their Cow's Milk-Based Products so as to maximize sales and profits at the expense of the health and safety of the public in conscious disregard of the foreseeable harm caused to preterm infants by their Cow's Milk-Based Products.

112. Defendants' conduct was intentional and/or wanton.

113. Defendants' conduct as described above, including, but not limited to, their failure to provide adequate warnings and their continued manufacture, sale, and marketing or their Cow's Milk-Based Products when they knew or should have known of the serious health risks to preterm infants, was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendants acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided under O.C.G.A. § 51-12-5.1. Accordingly, punitive damages should be imposed against Defendants pursuant O.C.G.A. § 51-12-5.1 and others applicable laws, to punish and deter Defendants from repeating or continuing such unlawful conduct.

COUNT VIII: WRONGFUL DEATH

114. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

115. As a result of the individual, combined and concurring acts and omissions of Defendants as set forth herein above caused or contributed to cause injuries to Baby Drye for which Plaintiff may recover. Such damages include damages which may be recovered for:

a. The homicide and wrongful death of Baby Drye, deceased, entitling Plaintiff to recover the full value of Baby Drye's life, as well as all other damages permitted under law;

b. Expenses associated with the last illness, death and burial of Baby Drye;

c. Pre-death physical injury, pain and suffering, disability, impairment, lost capacity to enjoy life, mental anguish, and lost earnings of Baby Drye in an amount to be proven at trial which may be recovered by Plaintiff; and

116. Pre-death medical expenses of Baby Drye in an amount to be proven at trial.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

(a) That process issue according to law;

(b) That Defendants be served with a copy of Plaintiff's Complaint For Damages and show cause why the prayers for relief requested by Plaintiff herein should not be granted;

(c) That Plaintiff be granted a **trial by jury** in this matter;

(d) That the Court enter a judgment against Defendants for all general and compensatory damages allowable to Plaintiff;

(e) That the Court enter a judgment against Defendants for all special damages allowable to Plaintiff;

(f) That the Court enter a judgment against Defendants serving to award Plaintiff punitive damages under the provisions of O.C.G.A. § 51-12-5.1;

(g) That Plaintiff recover all possible damages from the wrongful death of Baby Drye;

(h) That the Court enter a judgment against Defendants for all other relief sought by Plaintiff under this Complaint;

(i) That the costs of this action be cast upon Defendants; and

(j) That the Court grant Plaintiff such further relief which the Court deems just and appropriate.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted,

/s/ *C. Andrew Childers*
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